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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,042	03/31/2004	Friedrich Fuchs	P04,0077	7825
26574	7590	08/08/2007		
SCHIFF HARDIN, LLP PATENT DEPARTMENT 6600 SEARS TOWER CHICAGO, IL 60606-6473			EXAMINER LAURITZEN, AMANDA L	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 08/08/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/815,042	<b>Applicant(s)</b> FUCHS ET AL.	
	<b>Examiner</b> Amanda L. Lauritzen	<b>Art Unit</b> 3737	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-48 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*Response to Arguments*

Applicant's arguments filed 2 April 2007 have been fully considered but they are not persuasive. New grounds of rejection necessitated by amendment are presented herein.

1. Regarding applicability of the Schnall reference, the method of Schnall is specific to vasodilatation and vasoconstriction as a result of local heating and/or cooling (that results in a temperature change) or as a result of administering a pharmacological agent known to elicit constriction or dilation of the vessels as an alternative to occluding pressure [0020; also claim 23]. Arterial flow is measured following and dependent upon this temperature change. The method further includes application of a "non-occluding pressure" as presently claimed [0016].
2. Applicant asserts that there is no selective dilation or constriction in Schnall, but rather only constriction. Examiner disagrees and points out that the pharmacological agent or heating and/or cooling described at par. 20 are capable of eliciting a "peripheral vasodilatation or vasoconstriction" and are accordingly disclosed.
3. Applicant asserts that there is no need to obtain a measurement of a change in temperature in the Schnall; however, the Schnall reference was not relied upon for the temperature sensor or temperature measurement. Rather, Bailey et al. discloses a temperature sensor that provides controlled temperature measurement and regulation that could be incorporated in the cuff of Schnall [Bailey, 0375].

## DETAILED ACTION

### *Priority*

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

### *Claim Objections*

2. Claim 3 is objected to because it appears the term "vocalized" was intended as "localized". Applicant is advised to check the claims and specification for this and other informalities and correct as appropriate.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnall et al. (US 2004/0092832) in view of Bailey et al. (US 2001/0045104).

Schnall et al. disclose a method for examining the responsiveness of blood vessels comprising the steps of: producing a localized, controlled temperature change in a body part to selectively dilate or constrict vessels and measure fluid flow in the vessels after this temperature change, including radiantly heating (Abstract; also paras. 20, 88). Further, Schnall is particular to application of a "non-occluding pressure" [0016]. The heating and/or cooling disclosed by Schnall will also non-occludingly constrict vessels as a direct result. The method of Schnall is particular to measure of vascular flow after a temperature change and this has been interpreted to

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be a measurement that is dependent upon the temperature change, in that the temperature change necessarily precedes it. The method of Schnall includes application of a plurality of compresses, as in claim 21 in which *at least one* cuff is administered.

The method of Schnall includes steps of providing a localized, controlled temperature change and subsequently measuring fluid flow through the vessels but is not specific to how the local temperature change is accomplished. However, in order to solve the same problem of heating and cooling an externally applied compress or cuff, Bailey et al. disclose controlling temperature change with a Peltier element (para. 27) and further discloses varying temperature with water and/or oil (para. 527 for liquid-filled compresses). The device of Bailey further includes external storage containers with a valve to control fluid flow into the compress (refer to Fig. 1 for container 101, valve 102; also para. 459; Fig. 15; Figs. 17A-D). The fluids specified by Bailey are inert for magnetic resonance tomography. It would have been obvious to one of ordinary skill in the art at the time of invention to use the heating and cooling systems disclosed by Bailey et al. to produce a localized temperature change in the method of Schnall in order to provide a heat exchange system that self-regulates at a temperature above 0°C (in the case of using water at para. 527) and to provide a thermoelectric junction that can be exploited for electrochemical battery power (in the case of using a Peltier element for heat exchange at para. 450. In this case, the Peltier element is interacting with the heel).

Regarding claims 15 and 42 and 43, Bailey et al. disclose measuring a temperature of the body part using a temperature sensor (para. 375) and storing a plurality of recorded temperatures (see RAM and ROM of para. 650 for storing sensor inputs). It would have been obvious to one of ordinary skill in the art at the time of invention to combine a temperature sensor as taught by

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Bailey with the method and device for examining blood vessel responsiveness of Schnall in order to provide a feedback safety control system for regulating temperature (for motivation, see Bailey para. 375).

Regarding claim 16, both Bailey and Schnall are silent with regard to obtaining a temperature curve with respect to time, but providing a temperature-time curve would have been obvious to one of ordinary skill in the art at the time of invention in order to provide a convenient visual display of data.

Regarding claims 17 and 44, the disclosure of Schnall is silent with regard to providing an external imaging device, but the compress/ heat exchange system of Bailey is formed of non-metallic components and is to be used in conjunction with x-ray and other imaging modalities (paras. 147 and 209). It would have been obvious to incorporate use of any of a variety of imaging devices as taught by Bailey with the method of Schnall in order to simultaneously administer cryotherapy while performing diagnostic imaging (for motivation, see para. 209 of Bailey).

Regarding claims 21 and 47, Bailey discloses applying a plurality of compresses at different sides of a body part as in Fig. 20A where a plurality of bladders are provided that constitute different compresses. It would have been obvious to provide multiple compresses in order to provide different temperature set points at different target tissue areas (para. 510).

Regarding claims 25-29, both Schnall and Bailey are silent with regard to using angiography, but it would have been obvious to incorporate contrast vessel imaging methods in a method of evaluating vessel responsiveness to one having ordinary skill in the art in order to

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visualize the inner openings of the vessels, the size of the vessels (including cross-sectional area), as well as fluid flow within the vessels.

Regarding claim 30, a compress [cuff] of Schnall is configured for placement on a body part (containing vessels), and while the compress is disclosed to accomplish local heating and cooling resulting in a temperature change and “non-occluding constriction” [Schnall 0016], Schnall is not specific to this being accomplished with a temperature-adjustable fluid; however Bailey et al disclose temperature adjustable fluids (water and/or oil) [0257 for liquid-filled compresses]. It would have been obvious to one of ordinary skill in the art at the time of invention to use the liquid heating and cooling systems disclosed by Bailey et al to produce a localized temperature change in the method of Schnall in order to provide a heat exchange system that self-regulates at a temperature above 0°C (in the case of using water at para. 527) and to provide a thermoelectric junction that can be exploited for electrochemical battery power (in the case of using a Peltier element for heat exchange at para. 450. In this case, the Peltier element is interacting with the heel).

Regarding claims 35 and 41, Schnall is silent with regard to providing different fluid temperatures, but Bailey discloses providing a number of individually thermostatically controlled paths. It would have been obvious to one of ordinary skill in the art at the time of invention to provide different fluid temperatures as taught by Bailey with the method of Schnall in order to vary the temperature for different target tissue areas (Bailey para. 510 and para. 449 for controller device that maintains temperature differential).

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***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*af*

ALL

7/23/2007

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